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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,745	03/08/2001	Roman Turovskiy	257/049	8509

34263 7590 11/03/2003

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EXAMINER

ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 11/03/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/803,745

Applicant(s)

TUROVSKIY ET AL.

Examiner

Kathryn Odland

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,7,11,21,24,48,77, and 86-98 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6,8-10,22,23,25 and 61 is/are rejected.
- 7) ☒ Claim(s) 8 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 May 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I and Species 11 in Paper No. 11 is acknowledged. Claims 1-2, 4, 6, 8-10, 22-23, 25 and 61 are under consideration.

Information Disclosure Statement

Applicant has cited 3 articles in the IDS. These articles do not appear in the file.

Applicant is requested to provide a copy of the articles. They will be uninitialed in the signed copy of the IDS.

Specification

The amendments to the abstract are acknowledged and accepted.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: element 42 is not shown in figures 10A-10C. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: element 63. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the

Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claims 8 and 10 are objected to because of the following informalities: they depend from claim 7, which is a non-elected claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claim 25 recites the limitation "the tubular member" in line 16. There is insufficient antecedent basis for this limitation in the claim. Since there are two tubular members disclosed, it is unclear which tubular member is referenced.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 1-2, 4, 6, 8-10, 22-23, 25 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanganov et al. in US Patent No. 5,876,367.

Regarding claim 1, Kanganov et al. disclose a method for open surgical endarterectomy via providing an elongate member (such as 44) having a proximal end, a distal end, and an expandable filter (42) at the distal end, as recited in column 7, lines 5-25; inserting the distal end of the elongate member into the internal carotid artery

downstream of a lesion, as stated in column 7, lines 10-15 and seen in figure 5; expanding the filter, as recited in column 7, lines 20-25; inserting the proximal end of a tubular member (10/14) into the common carotid artery upstream of the lesion, as seen in figure 5; and flowing blood from the common carotid artery through a lumen of the tubular member (10/14) into the internal carotid artery, as discussed throughout the specification.

Applicant has not recited performing the methods steps in any particular order, such as step a, b, c or first, second, third, etc. Therefore, since applicant has not claimed a distinct order that the steps be completed, Kanganov et al. perform the steps stated above and thus accomplish the function of protecting debris from escaping.

Further, Kanganov et al. do not explicitly recite advancing a tubular member having proximal and distal ends over the elongate member to place the distal end of the tubular member within the internal carotid artery. However, it would be obvious to one with ordinary skill in the art and within the scope of the invention to advancing the tubular member having proximal and distal ends over the elongate member to place the distal end of the tubular member within the internal carotid artery although not explicitly recited. Kanganov et al. recite, "After the shunt is purged, proximal opening 12 is secured by a clamp (not shown). Filter catheter 43 having elongate member 44, filter mesh 42 is enlarged to cover substantially all of the cross-sectional area of the internal carotid artery lumen. Proximal opening 12 of shunt 10 is then inserted into common carotid artery 65 through an incision." Thus, which is inserted first would be obvious if not inherent to one with ordinary skill in the art to prevent debris from escaping. Further

applicant has not demonstrated the criticality or advantage to the particular order of steps.

Regarding claim 2, Kanganov et al. obviously disclose that as applied to claim 1 as well as an elongate member that is a wire, as recited in column 2, lines 33-37.

Regarding claim 8, although this claim depends from claim 7 the subject matter will be considered as though it depends from claim 1. Kanganov et al. obviously disclose that as applied to claim 1 as well as the carotid artery and internal carotid artery that are occluded by clamping, as discussed in columns 6-8 and seen in figure 5.

Regarding claim 9, Kanganov et al. obviously disclose that as applied to claim 1 as well as back-bleeding the tubular member to purge air, as recited in column 7, lines 5-25.

Regarding claim 10, although this claim depends from claim 7 the subject matter will be considered as though it depends from claim 1. Kanganov et al. obviously disclose that as applied to claim 1 as well as making an arteriotomy to access the lesion, as discussed throughout the specification.

Regarding claim 22, Kanganov et al. obviously disclose that as applied to claim 1 as well as a tubular member that has a port (16) between the proximal and distal ends, and wherein the elongate member is passed through the port as the tubular member is

advanced over the elongate member, as recited in column 7, lines 5-25 and seen in figure 5.

Regarding claim 23, Kanganov et al. obviously disclose that as applied to claim 22 as well as a port that includes a hemostatic valve (16), as recited in column 7, lines 5-25 and seen in figure 5.

Regarding claim 25, Kanganov et al. disclose a method for open surgical endarterectomy, via providing an elongate member (such as 44) having a proximal end, a distal end, and an expandable filter (42) at the distal end; inserting the distal end of the elongate member (such as 44) into the internal carotid artery downstream of a lesion, as recited in column 7, lines 5-25 and seen in figure 5; expanding the filter (42); inserting a proximal end of a tubular member (10/14) into the common carotid artery upstream of the lesion; and flowing blood from the common carotid artery through a lumen of the tubular member into the internal carotid artery, as discussed throughout the specification.

Applicant has not recited performing the methods steps in any particular order, such as step a, b, c or first, second, third, etc. Therefore, since applicant has not claimed a distinct order that the steps be completed, Kanganov et al. perform the steps stated above and thus accomplish the function of protecting debris from escaping.

Further, Kanganov et al. do not explicitly recite advancing a first tubular member having proximal and distal ends over the elongate member to place the distal end of the

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first tubular member within the internal carotid artery. However, it would be obvious to one with ordinary skill in the art and within the scope of the invention to advancing the tubular member having proximal and distal ends over the elongate member to place the distal end of the tubular member within the internal carotid artery although not explicitly recited. Kanganov et al. recite, "After the shunt is purged, proximal opening 12 is secured by a clamp (not shown). Filter catheter 43 having elongate member 44, filter mesh 42 is enlarged to cover substantially all of the cross-sectional area of the internal carotid artery lumen. Proximal opening 12 of shunt 10 is then inserted into common carotid artery 65 through an incision." Thus, which is inserted first would be obvious if not inherent to one with ordinary skill in the art to prevent debris from escaping. Further, applicant has not demonstrated the criticality or advantage to the particular order of steps.

Additionally, Kanganov et al. do not explicitly recite *joining* the distal end of the second tubular member (such as 14) to the proximal end of the first tubular member. On the other hand, it would have been obvious to one with ordinary skill in the art at the time the invention was made to make a tube separable, thus including the step of joining the tubes, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

Regarding claim 61, Kanganov et al. disclose a medical device for open surgical endarterectomy, having a first tubular member (14) having a proximal end, a distal end,

and a lumen therebetween communicating with a distal port (13), a first proximal port (intersection of 14 and 10), and a second proximal port (at 16); a hemostatic valve (16) mounted in the second proximal port, as seen in figure 5; a second tubular member (10) having a proximal end, a distal end, and a lumen therebetween; and an elongate member (44) inserted through the hemostatic valve (16) and the second proximal port, the elongate member having a proximal end, a distal end, and an expandable filter (42) at the distal end.

However, Kanganov et al. do not explicitly recite a distal end of the second tubular member that is adapted for releasable attachment to the first proximal port of the first tubular member. On the other hand, it would have been obvious to one with ordinary skill in the art at the time the invention was made a distal end of the second tubular member that is adapted for releasable attachment to the first proximal port of the first tubular member, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

9. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanganov et al. in US Patent NO. 5,876,367 in view of Hancock et al. in US Patent No. 6,610,077.

Regarding claim 4, Kanganov et al. obviously disclose that as applied to claim 1.

However, Kanganov et al. do not explicitly recite a filter that is slideably mounted on the

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elongate member. On the other hand, Hancock et al. teach a filter that is slideably mounted on the elongate member, as stated in column 9, lines 32-67. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Kanganov et al. to include a filter that is slideably mounted on the elongate member for the purpose of more flexibility.

Regarding claim 6, Kanganov et al. obviously disclose that as applied to claim 1 as well as a filter with a plurality of flexible struts, each strut bonded to the elongate member at a proximal end, as stated in column 5. However, Kanganov et al. do not explicitly recite each strut having a distal end slideably mounted on the elongate member. On the other hand, Hancock et al. teach a filter that is slideably mounted on the elongate member, as stated in column 9, lines 32-67. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Kanganov et al. to include each strut having a distal end that is slideably mounted on the elongate member for the purpose of more flexibility.

Conclusion

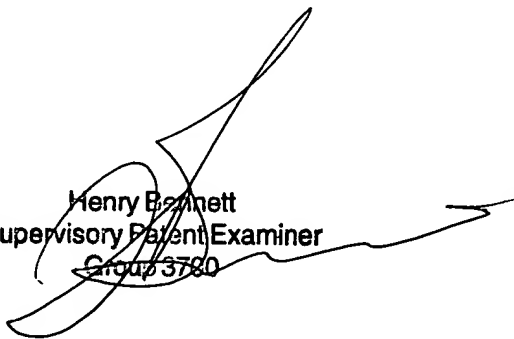
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2003/0120304; US 2002/0095141; US 2002/0062134; US Patent No. 6,551,268; US Patent No. 6,620,148; and US Patent No. 6,168,579.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO



Henry Bennett
Supervisory Patent Examiner
Group 3780